09/787342
Rec'd PCT/PTO 16 MAR 2001

INFUSION PUMP WITH A COMPUTER FOR CALCULATING THE MAXIMUM PERMITTED DELIVERY QUANTITY

The invention relates to an infusion pump for the delivery of a quantity of medicament to the body of a patient determinable by means of an electronic control device, the pump being provided with a computer for calculating the maximum permitted delivery quantity as a function of the previously delivered quantity and a blocking device for preventing further medicament delivery on exceeding a predetermined, permitted maximum value.

Such infusion pumps are used for supplying a patient with a medicament over a long time period and the medicament quantity continuously delivered by the infusion pump corresponding to the needs of the patient can be adjusted.

DE 33 90 462 C2 discloses an implantable infusion pump equipped with a computer, which determines the medicament quantity delivered over a "sliding time window/slot", e.g. over three hours and blocks further delivery if the quantity delivered over this time period exceeds a maximum value.

However, this procedure is adequate and the sliding time window length random. In many cases, such as e.g. with an attack of pain, it is necessary to briefly considerably raise the quantity of active substance to be delivered by the pump in order to rapidly raise the active substance level. However, whereas a quantity distributed over three hours can be tolerated, this can prove toxic when administered over three minutes. However, an infusion rate allowed when distributed over three hours, can prove toxic or even lethal when the administration extends beyond three hours. This problem cannot be solved with the "sliding time window".

The problem of the invention is to provide an implantable infusion pump making it possible to reliably determine the in each case allowed delivery quantity.

According to the invention this problem is solved in that the computer determines the quantity or concentration of the active substance in the body of the patient on the basis of the medicament quantity delivered and its breaking down in the body and compares it with the predetermined maximum value.

A preferred embodiment is characterized in that the computer is provided with a memory storing a quantity resulting from the adding up of the in each case delivered quantity and a subtraction of the percentage of the quantity entered in the memory resulting from the expected breaking down of the medicament in the body, as well as a comparator which constantly compares the quantity entered in the memory with the predetermined, permitted maximum

value.

The maximum value at which blocking takes place is consequently not, as in the case of the prior art, a value averaged out over a given time window, but is in the form of the integral reduced by the amount resulting from the half-life of the medicament over the total quantity delivered.

The computer is preferably provided with a device which, either with a time interval predetermined in accordance with the expected breaking down of the medicament in the body, brings about the subtraction of a specific percentage of the quantity entered in the memory, or in the case of fixed, predetermined time intervals brings about the subtraction of a percentage of the quantity entered in the memory corresponding to the expected breaking down of the medicament.

In the case of the proposed construction of the infusion pump it is ensured that the administration of the medicament, which is brought about by means of the control device by the doctor or optionally also the patient, does not exceed a maximum permitted value.

In order to adjust the device for a given patient, it is merely necessary to input the half-life of the medicament to be administered and the individually permitted maximum value (toxic threshold).

It is obvious that the device must also be programmed in such a way that the lower minimum value (action threshold) is maintained.

The pump can be an implantable infusion pump. It is also possible to place the computer (or an additional, parallel-operating computer) in an external control device. It is possible for a bolus administration (namely an infusion of the medicament which in the case of long-term administration would lead to the toxic threshold being exceeded) only being possible in the case of electromagnetic coupling with the control device.

The invention is described in greater detail hereinafter relative to the drawing. The drawing shows in the lower graph an infusion profile and in the upper graph the pattern, resulting from this infusion profile, of the quantity entered in the memory, the expected quantity (and therefore the concentration) of the active substance in the body of the patient, as well as the predetermined, permitted maximum value (threshold S).

In the case of the infusion profile shown there is initially a long-term administration with a relatively low infusion rate. As from time t1 to t2 (caused by the patient or doctor) a first bolus administration takes place, i.e. a brief administration with a high infusion rate, such as is e.g.

necessary if the patient suffers an acute attack. At time t3 switching to a higher infusion rate takes place. At time t4, using the control device, the administration of a bolus is brought about which, on reaching the predetermined threshold S is prematurely stopped at time t5 by the computer. At time t6 the user attempts to set a bolus administration, which is stopped at time t6 because the threshold S has been reached.

The path of the active substance concentration in the body of the patient resulting from this infusion profile and which is essentially proportional to the active substance quantity present in the body is shown in the lower graph.

The pattern of the active substance concentration is represented by a time integral over the infused quantity, reduced by the breaking down resulting from the half-life of the substance, i.e. as a function with a linear term determined by medicament administration and a negative exponential term determined by the medicament breaking down rate.

In the drawing this leads up to time t1 to a constant path, because here the quantity supplied precisely corresponds to the quantity broken down by the body. The administration of the bolus at time t1 leads to a steep rise in the active substance concentration. At the end of bolus administration at time t2 the concentration continuously drops, because the supplied active substance quantity is lower than the broken down quantity. After doubling the infusion rate at time t3 the concentration constantly rises, but with a shallower rise.

The bringing about of a further bolus administration through the user or doctor at time t4 leads to a concentration rise up to the threshold at time t5, which at time t6 leas to an automatic termination of bolus administration by the computer. The attempt at time t7 to bring about a further bolus administration is immediately prevented by the computer due to the immediate reaching of the threshold.

The path of the active substance concentration is simulated in the computer of the implantable infusion pump (which can also be located in the control device).

In predetermined time intervals, e.g. every 10 sec, the quantity entered in the memory of the infusion pump is increased by a quantity corresponding to the amount delivered by the infusion pump in this time period. Furthermore a mathematically determined percentage of the quantity entered in the memory is subtracted from the half-life of the delivered medicament, the resulting quantity is stored as the actual value. Alternatively in time intervals given by the half-life (i.e. more frequently with a shorter half-life and

less frequently with a longer half-life), the amount delivered in this time period can be summated and a fixed quantity subtracted.

The value entered in the memory consequently always corresponds (due to the not precisely determinable half-life this is naturally only approximately) to the in each case actual amount or concentration of the active substance in the body of the patient, whilst taking account of the breaking down thereof.